

NOTE: All Systems Should be Considered as Investigational-Use Only in the Context of the NIH BRAIN Initiative. Protocol Support is Subject to QiG Approval.

Exhibit C -- NEURONEXUS MATERIALS

Clinical investigators are advised to contact Daryl Kipke, PhD at NeuroNexus for updated information on NeuroNexus BRAIN platform system (dkipke@neuronexus.com; 734-913-8858)

NeuroNexus (<http://neuronexus.com>) develops and commercializes high-value neural interface technology, components, and systems for neuroscience and clinical applications. NeuroNexus is a subsidiary of Greatbatch, Ltd., a large publicly traded medical device and manufacturing company, (<http://greatbatch.com>).

As part of the NIH BRAIN program, NeuroNexus will provide an advanced neural interfacing platform system including both electrodes and systems for neurostimulation and neural recording. The NeuroNexus BRAIN platform system is based on established, well-validated components and technologies that are either currently available or under active development by NeuroNexus and the QiG Group of Greatbatch, the parent corporation of NeuroNexus. The system includes both off-the-shelf devices and devices that are under active development for several clinical applications.

The NeuroNexus BRAIN platform system is powerful, flexible, and can be readily configured to meet particular requirements over a broad range of exploratory clinical studies. NeuroNexus expects to work closely with clinical investigators to identify project-specific device requirements and provide appropriately configured devices. NeuroNexus should be contacted for updated information on the BRAIN platform.

The NeuroNexus BRAIN platform includes both sophisticated conventional neurostimulation leads and innovative high-definition electrode arrays that are optimized for interfacing with a particular neural target. NeuroNexus can also provide hybrid electrode systems from these two electrode platforms to meet application requirements. Table 1 summarizes the electrode / lead platform. Table 3 highlights representative types of electrode arrays that can be used to target surface, shallow, and deep neural structures in the brain and spinal cord.

Table 1. Summary of Electrodes/Leads in the NeuroNexus BRAIN platform.

	Conventional neurostimulation leads	High-definition electrode arrays	Hybrid electrode assemblies
On-label indications per directions for use	Epidural spinal cord stimulation for treatment of chronic pain	Application specific-- Neural recording, neurostimulation	n/a
Summary specifications	<ul style="list-style-type: none">• 8- and 12-contact leads• Percutaneous leads• Surgical/paddle types	<ul style="list-style-type: none">• Modular configurations• 2 to 128 channels• Stimulation (macro and micro)	

		<ul style="list-style-type: none"> • Recording – EEG, evoked potentials, local field potentials, spikes • Epi-dural, • sub-dural • Penetrating -- deep brain, intra-cortical, and intra-spinal targets 	
PMA	No (in process)	No	n/a
CE Mark	Yes	No	n/a
Under development	No	Yes	Yes
Pre-clinical safety data available	Yes	Yes	n/a

The NeuroNexus BRAIN platform includes systems for both neurostimulation and neural recording (Table 2).

Table 2. Summary of neurostimulation and neural recording systems of the NeuroNexus BRAIN platform.

	Neurostimulation system	Neural recording system	Integrated neurostimulation and recording
On-label indications per directions for use	Epidural spinal cord stimulation for treatment of chronic pain	General purpose – EEG, evoked potentials, local field potentials, spiking activity	tbd
Summary specifications	<ul style="list-style-type: none"> • 24 channels; • Independent current-controlled • Broad parameter ranges (frequency, amplitude) • Arbitrary waveforms • External package (wireless, rechargeable) • Implantable package available • Sophisticated clinical programmer • Fully programmable • IPG available, with restrictions 	<ul style="list-style-type: none"> • Up to 256 channels • High-fidelity and high-bandwidth recording of fields and spikes • External system • Portable, wearable package • Flexible online signal analysis options • Offline data analysis and visualization • Sophisticated user interface • Advanced options for miniaturization 	<ul style="list-style-type: none"> • Combination of neurostimulation and neural recording specifications • Synchronized, fully integrated recording and stimulation functionality
PMA	No (in process)	No	n/a
CE Mark	Yes	No	n/a
Under development	Yes	Yes	Yes
Pre-clinical safety data available	Yes	Yes	Yes

Table 3. Illustrative reference designs of electrode arrays in the NeuroNexus BRAIN platform.

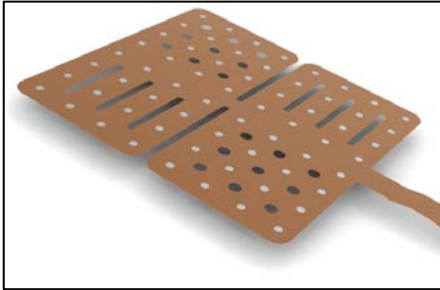
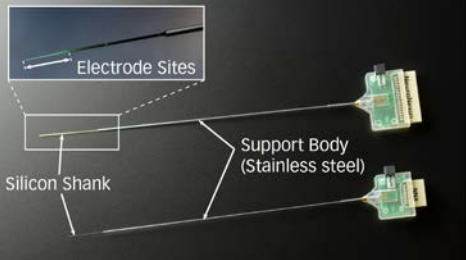
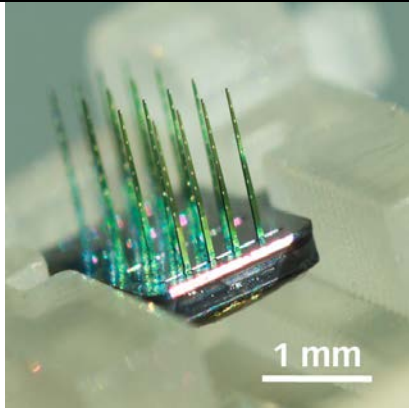
Neural targets	Reference design	Description
Brain surface Spinal cord surface (sub-dural or epidural)		High-definition (HD) grid array for neural mapping (clinical version) This thin, highly conformal electrode platform is based on a 64-channel “module” that can be custom-designed for target-specific site layouts. Substrate slots can be designed for increased mechanical flexibility and fluid management
Deep brain structures		Vector electrode (clinical version) This electrode platform provides a high-quality microelectrode array packaged to provide precise access to deep brain structures for recording and/or stimulation.
Intra-cortical structures Intra-spinal structures		Matrix electrode (clinical version) This electrode platform provides 3D microelectrode array technology for neural recording and stimulation from cortical or shallow structures. The 3D electrode site layout can be purpose-designed for targeting specific neural structures.

Exhibit D -- NEURONEXUS SUPPORT

NeuroNexus will be available to provide full technical support to its research collaborators through all stages of the project, from project inception and proposal preparation through the clinical studies. The NeuroNexus team has extensive NIH project experience.

The NeuroNexus support may include

- Custom design services
- Technical support and consulting on engineering and scientific components of the study
- Participation in research publications
- Intellectual property strategy and preparation
- Commercial partnering and translational strategy